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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/067,638	04/28/1998	LEX M. COWSERT	ISIS-2960	1414

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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/067,638

Applicant(s)

COWSERT ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2004 and 07 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 83-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 83-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>(4 sheets)</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants' arguments, filed 2/24/04 and 6/7/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

PRIOR ART

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 83 and 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agrafiotis et al. (P/N 5,463,564); taken in view of Hyndman et al. [Biotechniques 20(6):1090 (1996)] and Nickerson et al. [PNAS 87 :8923 (1990)].

This rejection is reiterated and maintained from the previous office action, mailed 8/25/03. Applicants argue that the combination of references do not teach all of the elements of the claims, specifically preparing a set of oligonucleotides that modulate

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expression of a selected nucleic acid. In response the combination of references includes Hyndman et al. which was noted in the previous office action, mailed 8/25/03, as citing a desired oligonucleotide those which provide antisense inhibition of gene expression on page 1090. Thus, the reference combination does, in fact, teach oligonucleotides that modulate expression of a selected nucleic acid as is well known for antisense oligonucleotides. Applicants then argues that Agrafiotis et al. teaches away from the instant invention via random bio-oligomers therein further described directed to additionally iterated optimization based on test results. In response Agrafiotis et al. proceeds to design of a virtual library directed to particular desired properties thereof from a larger random library. Many such properties are possible, merely directed as desired. Thus, Agrafiotis et al. is generic regarding what desired property is the goal of the Agrafiotis et al. system and motivates whatever is desired in the art. Hyndman et al. is also directed to oligonucleotide design but specifically indicates antisense oligonucleotides that are modulatory to selected nucleic acid target expression. Thus, the combination of references clearly suggests and motivates antisense oligonucleotide design and preparation as well as testing as noted above contrary to the arguments of applicants which are therefore non-persuasive. Applicants then summarize Hyndman et al. as further detailing antisense oligomer design which is acknowledged but only supports this rejection and thus is non-persuasive. Applicants then argue that Agrafiotis et al. with Hyndman et al. lacks description of the claimed system. This is non-persuasive as the rejection is based on the above combination of references and not on only Agrafiotis et al. with Hyndman et al. and thus the argument

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is not directed to the basis for the rejection. Applicants then argue Nickerson et al. by admitting that it teaches automated testing as in the instant claims but that it does not teach or suggest the other instant claim limitations. This argument again is non-persuasive as not being directed to the basis of the rejection which relies on the above cited combination of references and not any one alone.

In summary, the rejection summarized above is still deemed proper.

Claims 83-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agrafiotis et al. (P/N 5,463,564); taken in view of Hyndman et al. [Biotechniques 20(6):1090 (1996)] and Nickerson et al. [PNAS 87 :8923 (1990)]; taken further in view of either of Albertsen et al. (P/N 5,352,775) or Cutting et al. (P/N 5,407,796) regarding certain specific functional target regions in instant claim 84.

This rejection is reiterated and maintained from the previous office action, mailed 8/25/03. Applicants then apparently argue that Cutting et al. lacks description of the claimed system. This is non-persuasive as the rejection is based on the above combination of references and not on only one of the references alone and thus the argument is not directed to the basis for the rejection. Applicants argue that Cutting et al. by admitting that it teaches specific target testing as in the instant claims but that it does not teach or suggest the other instant claim limitations. This argument again is non-persuasive as not being directed to the basis of the rejection which relies on the above cited combination of references and not any one alone.

PROVISIONAL OBVIOUSNESS-TYPE DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 83 and 85-87 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 55, 56, 58-72, 74-87, and 99-102 of copending Application No. 09/295,463. Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons of record which have not been argued by applicants and is therefore maintained and reiterated from the previous office action, mailed 8/25/03.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

INFORMATION DISCLOSURE STATEMENTS

Several citations are lined through on the enclosed PTO Forms 1449 to avoid duplication of citation from previous PTO Forms 1449. The citation Numbered 254 on the PTO Form 1449, filed 6/9/03 is lined through due to being in a foreign language and therefore not readable for consideration.

No claim is allowed.

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THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 6, 2004

Ardin H. Marschel 9/6/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER